Message

From: Giacalone, Robert [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=ROBERT.GIACALONE]
Sent: 1/25/2016 7:57:44 PM
To: Callinicos, Sean [/O=CAH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Callinicos, Sean5fd]
Subject: DEA related documents and links
Attachments: 04b DEA Guidance Letters.pdf; 05a DEA MOA 2008 CAH and 2012.pdf

Sean,

Please see attached DEA guidance letters I referenced along with past DEA actions and Cardinal Health – DEA/DOJ settlement documents in those matters.

In addition, the following links provide past DEA presentations to:

(a) Distributors: http://deadiversion.usdoj.gov/mtgs/distributor/index.html
(b) Pharmacies: http://deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html
(c) Manufacturers: http://deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html

Also, Cardinal Health along with other industry members (i.e., Mallinckrodt, Endo, Actavis, ABC, and McKesson) have worked closely with the National Association of Boards of Pharmacy to create a video to help educate pharmacists on drug diversion (Red Flags video). We got a plug in their press release and a mention in the video.

https://www.nabp.net/news/new-educational-video-for-pharmacists-addresses-prescription-drug-abuse (press release)

https://www.youtube.com/watch?v=WY9BDgcdxaM&feature=youtu.be (red flags video)

Also, over 30 state pharmacy boards have our video posted on their website (e.g., Ohio State Pharmacy Board version: https://www.youtube.com/watch?v=WY2I2JE3Hqs).

Lastly, we worked with NABP and a number of associations (e.g., NACDS, AMA, NCPA, APhA and even DEA) to create a consensus stakeholder document advising all parts of the healthcare chain (e.g., prescribers, pharmacists, wholesalers, manufacturers) on how best to interact to address prescription drug diversion:

https://www.nabp.net/news/nabp-stakeholders-release-consensus-document-on-the-challenges-and-red-flag-warning-signs-related-to-prescribing-and-dispensing-controlled-substances

Please let me know if you have any questions or need anything further.

CardinalHealth

Robert P. Giacalone, RPh, JD
SVP, Regulatory Affairs & Chief Regulatory Counsel
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robert.giacalone@cardinalhealth.com

From: Callinicos, Sean
Sent: Monday, January 25, 2016 11:23 AM
To: Giacalone, Robert
Subject: very helpful...good talking to you today....

http://www.newyorker.com/magazine/2014/05/05/prescription-for-disaster

PLAINTIFFS TRIAL EXHIBIT
P-08873_00001

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U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JUN 12 2012

Dear Registrant:

This letter is being sent to every entity in the United States who is registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. This letter is to remind controlled substance manufacturers and distributors of their responsibility to inform DEA of suspicious orders in accordance with 21 Code of Federal Regulations (C.F.R.) § 1301.74(b).

On September 27, 2006, DEA sent a letter to this registrant community expressing concerns regarding drug abuse in the United States and highlighted the responsibility of manufacturers and distributors to be vigilant in the distribution of controlled substances. To assist manufacturers and distributors, DEA listed circumstances that might be indicative of diversion. On December 27, 2007, DEA issued another letter which reiterated the responsibility of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b). Although DEA's September 2006 letter included a list of factors that might indicate diversion, DEA wants to stress that this was not a comprehensive list of all possible indications of diversion. DEA encourages registrants to take an integrated approach. This point was emphasized in the December 2007 letter, and DEA is once again bringing it to your attention.

Under federal law, all manufacturers and distributors are required to maintain effective controls against diversion. 21 United States Code (U.S.C.) § 823. DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Specifically, 21 C.F.R. § 1301.74(b) states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." This regulation clearly places the responsibility on the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.

The registrant is also required to inform the local DEA Field Division Office of suspicious orders when discovered. The regulation provides examples of suspicious orders such as orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants who rely on rigid formulas to identify whether an order is suspicious may fail to detect suspicious orders. For example, this system might not identify suspicious orders placed by a pharmacy, if that pharmacy placed unusually large orders from the beginning of its relationship with the supplier. This system might not identify orders as suspicious if the orders were solely for one highly abused controlled substance. It should be noted that ordering one highly abused controlled substance and little or nothing else may indicate a deviation from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with the DEA Field Division Office that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant to their local DEA office and labeled as "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports." If the registrant determines the order is suspicious, the order may not be shipped and this suspicion must be reported to the local DEA Field Division Office.

Registrants who routinely report suspicious orders, yet fill these orders without first ascertaining that the order will not be diverted into other than legitimate medical, scientific, or industrial channels, are failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration. DEA may also pursue civil and criminal sanctions.

For more information regarding your obligation to report suspicious orders pursuant to 21 C.F.R. § 1301.74(b), please review the Final Order issued by the DEA Deputy Administrator in the matter of Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007). This document reiterates the duty to report suspicious orders when discovered by the registrant, and provides some criteria to use when determining whether an order is suspicious. The Final Order also specifically discusses a registrant's obligation to maintain effective controls against the diversion of controlled substances. You may obtain a copy of this Final Order, along with other information provided by the Office of Diversion Control, at www.DEAdiversion.usdoj.gov.

As always, it is DEA's goal to work in cooperation with the regulated community. DEA seeks to educate its registrants on their responsibilities and obligations under federal laws and regulations to ensure that controlled substances are used for legitimate purposes and to prevent diversion. Your role in the proper handling of controlled substances is critical for public safety as it helps to protect society against drug abuse and diversion.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

December 27, 2007

In reference to registration

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

February 7, 2007

In reference to registration

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005); available at www.drugabuse.gov/PDF/RRPrescription.pdf

[2] 21 U.S.C. 801(2)

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g. , ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

September 27, 2006

In reference to registration #

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005); available at www.drugabuse.gov/PDF/RRPrescription.pdf

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Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

[redacted]

2012 DEA MOA for CAH

[redacted]

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., ("Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all 28 Cardinal DEA registered distribution facilities.

BACKGROUND

1. Cardinal is registered with DEA at 28 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" or "the Act"). See Appendix A.

2. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"). See Appendix B.

3. Cardinal's Lakeland distribution facility ("Cardinal Lakeland") is registered with DEA as a distributor of Schedule II-V controlled substances at 2045 Interstate Drive, Lakeland, Florida 33805, with an expiration date of May 31, 2012.

4. On February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland. See Appendix C.

5. The Order to Show Cause referenced above alleged, among other things, that:

   a. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;

   b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and

   c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.

STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, as well as the facts alleged in the Government's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, constitute grounds under which DEA could revoke the DEA registration of Cardinal Lakeland. Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate. In lieu of continuing proceedings to revoke the DEA registration of Cardinal Lakeland, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters involving the conduct described in the Order to Show Cause, as well as DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this administrative matter.

2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. Conduct alleged in the February 2, 2012 Order to Show Cause ("Order to Show Cause"), and in DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D;

b. Failure to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels, including failing to conduct site visits of its retail pharmacy chain customers on or before May 14, 2012;

c. Failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before May 14, 2012; and

d. Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.

3. Effect of 2008 MOA. The obligations contained in the 2008 MOA are superseded by the obligations contained within this Agreement.

4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of Cardinal.

   a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1.f. This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this Agreement do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

   b. Within 120 days of the Effective Date of this Agreement, for all states, excluding Florida, Cardinal will commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances that are known to be diverted, or should be known to be diverted, at the time of the orders that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted. For Florida pharmacies, retail and chain, Cardinal, within 20 days of the Effective Date of this Agreement, will commence these site visit procedures. Cardinal will also employ additional field inspectors to perform investigations of Florida pharmacies.

      Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.

   c. Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.

d. Cardinal will enhance existing processes and practices for conducting due diligence reviews of pharmacies, chain and retail, including those located in Florida.

e. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, as well as tramadol, through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.

g. Cardinal agrees to the continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014, so long as the provisions of II.2.c are met.

h. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b).

i. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement

authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

j. Any material breach by any Cardinal facility of subsections II.1.a-f of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate of registration for that facility.

k. Cardinal agrees that it will dismiss, with prejudice, the pending appeal by Cardinal in Case No. 12-5061 as well as the pending petition for review by Cardinal in Case No. 12-1126 in the United States Court of Appeals for the District of Columbia Circuit. Cardinal agrees that it will also dismiss, with prejudice, Case No. 12-cv-185 in the United States District Court of the District of Columbia.

2. Obligations of DEA.

a. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and as described in subsection II.1.g. of this Agreement. DEA agrees to waive the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Offices.

b. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

c. If Cardinal is in compliance with the terms of this Agreement, DEA agrees that it will take appropriate steps to lift the suspension of Cardinal Lakeland's DEA registration and, if needed, to grant any requisite registration renewal on May 14, 2014.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Cardinal Lakeland in *The Matter of Cardinal Health*, DEA Docket No. 12-32.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its subsidiary entities, distribution facilities, and registrants that are listed in Appendix A, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 for the conduct alleged in the Order to Show Cause, DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, and for the conduct alleged in this Agreement; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of May 14, 2012, and the review of the reports and records Cardinal submitted to DEA prior to May 14, 2012. This release applies only to administrative actions brought before or by the Agency.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. DEA expressly reserves the right to pursue civil action, through the United States Attorney's Office, against Cardinal for the "Covered Conduct" as described in this Agreement. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Cardinal is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability other than administrative claims released in Paragraph II.4.a. and b.; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices to Cardinal pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Gilberto Quintero, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614-757-6597; email: gilberto.quintero@cardinalhealth.com;

b. With copy to: Steve Falk, Executive Vice-President and General Counsel, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614-652-7325; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of Cardinal Health:

_____
Craig S. Morford
Chief Legal and Compliance Officer

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Administrator

Dated: 5/14/12

Wendy H. Goggin
Chief Counsel

Dated: 5/14/12

APPENDIX A

(Cardinal Distribution Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.

2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.

3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.

4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (dba Specialty Pharmaceutical).

5. 2512 Westcott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.

6. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.

7. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.

8. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.

9. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (dba Specialty Pharmaceutical).

10. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.

11. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.

12. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.

13. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

14. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.

15. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.

16. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.

17. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.

18. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.

19. 4 Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.

20. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW0263056.

21. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.

22. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.

23. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.

24. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.

25. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (dba Parmed Pharmaceuticals).

26. Centro Internacional de Distribucion, EDIF#10, CARR. 869 KM. 4.2, Guaynabo, Puerto Rico, operating under DEA registration number RB0374683 (dba Borschow Hospital & Medical Supplies).

27. 15 Ingram Boulevard, Suite 140, La Vergne, TN, operating under DEA registration number RC0403802.

28. 152-35 10th Avenue, Whitestone, NY, operating under DEA registration number RK0416900 (dba Kinray, Inc.).

APPENDIX B

(2008 MOA Referenced in Background at Para. 2 of this Agreement)

[redacted]

2012 DEA Show Cause/ISO

[redacted]

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, Va 22152

FEB 0 2 2012

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Cardinal") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RC0182080, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Cardinal an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, or a location designated by the Administrative Law Judge, on April 3, 2012 (if Cardinal requests such a hearing), as to why DEA should not revoke Cardinal's DEA Certificate of Registration RC0182080, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(f), because Cardinal's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Cardinal is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA Certificate of Registration RC0182080 expires by its terms on August 31, 2012.

2. On September 30, 2008, Cardinal entered into an Administrative Memorandum of Agreement (MOA) with DEA agreeing to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Furthermore, Cardinal "acknowledg[ed] and agree[d] that the obligations undertaken ... do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for

controlled substances." MOA, at 3.

3. Despite the MOA, the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

4. Since at least 2009, Cardinal's largest purchasers of oxycodone products have been retail pharmacies in the State of Florida engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than a legitimate medical purpose and outside the usual course of professional practice.

a. From January 1, 2008 through December 31, 2011, Automation of Reports and Consolidated Orders System ("ARCOS") data shows that Cardinal's sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. In 2010 and 2011 alone, Cardinal sold 10.9 million dosage units of oxycodone to its top four customers. From 2008 to 2009, Cardinal's sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacy customers increased approximately 162%.

   The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal's Florida retail pharmacies, which received, on average, approximately 5,347 dosage units of oxycodone per month.

b. From January 1, 2008 through December 31, 2011, Cardinal sold over 5 million dosage units of oxycodone to its top customer, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy # 00219 ("CVS 219") (DEA Certificate of Registration BC5289055). On average, Cardinal sold CVS 219 approximately 137,994 dosage units of oxycodone per month during the same time period.

c. From January 1, 2008 through September 30, 2011, Cardinal sold approximately 3.4 million dosage units of oxycodone to Gulf Coast Pharmacy (former DEA Certificate of Registration BG8830223). On average, Cardinal sold Gulf Coast Pharmacy approximately 96,664 dosage units of oxycodone per month during the same time period.

d. From January 1, 2008 through December 31, 2011, Cardinal sold approximately 2.2 million dosage units of oxycodone to Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #05195 ("CVS 5195") (DEA Certificate of Registration BC6988298). On average, Cardinal sold CVS 5195 approximately 58,223 dosage units of oxycodone per month during the same time period.

e. From January 1, 2008 through September 30, 2011, Cardinal sold approximately 2.1 million dosage units of oxycodone to Caremed Health Corporation, d/b/a Brooks Pharmacy ("Brooks Pharmacy") (former DEA Certificate of Registration BC7126457). On average, Cardinal sold Brooks Pharmacy approximately 59,264 dosage units of oxycodone per month during the same time period.

5. Notwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers. Furthermore, Cardinal failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 C.F.R. §1301.74(b). In addition, Cardinal's conduct described herein violated the provisions of the Administrative Memorandum of Agreement.

6. In addition to the legal authorities cited above, the following Final Order provides a summary of the legal basis for this action: *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), it is my preliminary finding that Cardinal's continued registration is inconsistent with the public interest. Under the facts and circumstances described herein, it is my conclusion that Cardinal's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Cardinal possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Cardinal's DEA Certificate of Registration RC0182080 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Cardinal may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Cardinal fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Cardinal may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Cardinal decline to file a request for a hearing or, should Cardinal request a hearing and then fail to appear at the designated hearing, Cardinal shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.

Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Dedra S. Curteman, Counsel for the Government
Carrie A. Bland, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

[redacted]

2008 DEA MOA for CAH

[redacted]

SETTLEMENT AND RELEASE AGREEMENT
AND
ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Appendix A to this Agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all Cardinal DEA registered facilities identified in Appendix A.

BACKGROUND

1. Cardinal is registered with DEA at 27 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" of "the Act"). See Appendix A.

2. On November 28, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 801 C Street NW, Suite B, Auburn, Washington 98001 ("Auburn Facility"). See Appendix B.

3. On December 5, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 2045 Interstate Drive, Lakeland, Florida 33805 ("Lakeland Facility"). See Appendix C.

4. On December 7, 2007, the DEA, by its Deputy Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal, with respect to its distribution facility located at 1120 Commerce Boulevard, Swedesboro, New Jersey 08085 ("Swedesboro Facility"). See Appendix D.

5. On January 30, 2008, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause to Cardinal, with respect to its distribution facility located at 13651 Dublin Court, Stafford, Texas 77477 ("Stafford Facility"). See Appendix E.

6. The Orders to Show Cause referenced above alleged, among other things, that Cardinal failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal.

7. DEA also alleges that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located at the following addresses:

a. 500 Jerry Steele Lane, McDonough, Georgia 30253 ("McDonough Facility").

b. 27680 Avenue Mentry, Valencia, California 91355 ("Valencia Facility").

c. 4875 Florence Street, Denver, Colorado 80238 ("Denver Facility").

8. DEA alleges that Cardinal failed to report suspicious orders of controlled substances as more fully set forth in Appendix F, Paragraph 8 as required by 21 C.F.R. § 1301.74(b) .

9. The Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances.

STIPULATION AND AGREEMENT

The facts alleged in the Orders to Show Cause and the facts alleged in paragraphs 7 and 8 above as otherwise summarized above, if proven at an administrative hearing, could constitute grounds for revoking the DEA registrations of the facilities referenced in paragraphs 2-5 and 7 above. In lieu of continuing proceedings to revoke the DEA registrations for the facilities referenced in paragraphs 2-5 and 7 above, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, all outstanding administrative claims and/or issues with respect to the alleged failure of Cardinal to detect and report suspicious orders and the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances on or prior to September 30, 2008, including but not limited to the conduct described in the Orders to Show Cause, and all outstanding claims and or issues with respect to the allegations set forth in paragraphs 7 and 8 above. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete, just, and equitable resolution of this administrative matter.

2. No Admission or Concession. This Agreement is neither an admission by Cardinal of liability or of the veracity of any allegation made by DEA in the Orders to Show Cause, this Agreement or any investigation, nor a concession by DEA that its allegations in the Orders to Show Cause and investigations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. the conduct alleged in the Orders to Show Cause (Appendices B-E);

b. the alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, at all distribution facilities listed in Appendix A operated, owned, or controlled by it;

c. the conduct described in Appendix F, Paragraph 8 to this Agreement; and

d. the alleged failure of Cardinal to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before September 30, 2008.

II. Terms and Conditions

1. Obligations of Cardinal.

a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II(1)(c). This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

b. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, carisoprodol, and tramadol through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). Cardinal shall begin transmitting this information for all controlled substances no later than 90 days after the Parties have mutually agreed upon a format and as soon as practicable

for carisoprodol and tramadol. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

c. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within thirty days of the Effective Date of this Agreement that Cardinal will no longer be required to provide suspicious order reports or any other type of report regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty days written notice.

d. Cardinal agrees to the continued suspension of its authority to handle controlled substances at its Lakeland, Auburn, and Swedesboro facilities until October 1, 2008, or until such time that the parties execute this Agreement and the Settlement Agreement at Appendix F, whichever is later.

e. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).

f. Cardinal agrees that within 180 days of the Effective Date of this Agreement it will review distributions of oxycodone, hydrocodone, alprazolam, and phentermine to retail pharmacy customers and physicians for the 18-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of oxycodone, hydrocodone, alprazolam, and phentermine exceeded the thresholds established in its compliance program on the date of such review. To the extent it has not otherwise done so, Cardinal shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Cardinal's compliance program.

g. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the

rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

h. Cardinal agrees to pay to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) the amount of $34,000,000.00 in settlement of claims or potential claims for civil penalties made by the United States of America for failing to report suspicious orders of controlled substances. Payment of said amounts shall be made by Cardinal in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix F, Paragraph 13. Cardinal agrees to execute the Settlement Agreement at Appendix F simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said amounts within 30 days of the Effective Date of this Agreement.

i. Any material breach by any Cardinal facility of subsections II(1)(a)-(h) of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate(s) of registration for that facility.

2. Obligations of DEA.

a. At Cardinal's request, DEA shall provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members and Cardinal employees at Cardinal trade shows, or at Cardinal internal training sessions, and through written materials. The frequency and content of such training shall be at DEA's sole discretion.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II(1)(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.

c. Within 150 days of the Effective Date of this Agreement, but not earlier than the later of 90 days after the Effective Date of this Agreement, or 30 days after the previously suspended distribution center re-commences distribution of controlled substances, DEA shall conduct reviews of the functionality of Cardinal's diversion compliance program ("Compliance Reviews") at up to seven Cardinal

distribution centers, consisting of the Auburn Facility; the Lakeland Facility; the Stafford Facility; the Swedesboro facility; and two other Cardinal distribution centers selected by DEA, as well as the Controlled Substance Anti-Diversion investigatory files and processes maintained at Cardinal's Dublin, Ohio headquarters. DEA shall also review the investigatory files maintained by Cardinal of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify Cardinal no less than 48 hours prior to commencing a Compliance Review at a distribution center or at Cardinal's Dublin, Ohio headquarters. DEA shall issue a Notice of Inspection to Cardinal upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, Cardinal shall provide DEA with information in a form reasonably agreed to related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate Cardinal representative to provide DEA's preliminary conclusions regarding the Compliance Review. The parties agree that, at Cardinal's option, Cardinal may be represented by counsel at such Compliance Reviews and that DEA shall neither object to nor limit the number of counsel present at such Compliance Reviews.

d. The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to Cardinal on or before 165 days from the Effective Date of Agreement, stating that Cardinal failed to meet any of the requirements in either subsections II(2)(d)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with Cardinal within 48 hours regarding such a finding. DEA shall consider remedial measures that Cardinal has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.

e. DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix F.

f. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA

shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

g. DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to September 30, 2008, which may allege that Cardinal failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by Cardinal to DEA on or before September 30, 2008, for indications that Cardinal may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix F, Paragraph 8) occurring before September 30, 2008, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.

h. DEA represents that upon execution of this Agreement, Cardinal's pending application for renewals of the controlled substance registrations of the Auburn, Swedesboro, Lakeland, and Stafford facilities will be granted.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Auburn, Lakeland, Swedesboro, and Stafford facilities.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders to Show Cause and this Agreement; and

b. Refrain from filing any administrative claims against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of September 30, 2008, and the review of the reports and records Cardinal submitted to DEA prior to September 30, 2008.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further,

nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that Cardinal's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than

those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to paragraphs II(2)(c) and (d) of this Agreement to Cardinal shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Mark Hartman, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614 757 6597; email: mark.hartman@cardinalhealth.com;
b. With copy to: Steve Falk, General Counsel – HSCS, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614 757 5051; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

Kerry Clark
Chairman and Chief Executive Officer

Dated:

Ivan Fong
Chief Legal Officer and Secretary

Dated:

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated:

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated: 9/26/08

FOR Wendy H. Goggin
Chief Counsel

Dated: 10/2/08

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

On Behalf of Cardinal Health:

R. Kerry Clark
Chairman and Chief Executive Officer

Dated: 9/30/2008

Ivan K. Fong
Chief Legal Officer and Secretary

Dated: Sept. 30, 2008

John J. Carney, Esq.
Baker & Hostetler LLP
45 Rockefeller Plaza
11th Floor
New York, NY 10111
Counsel for Cardinal Health

Dated: 09-30-08

Jodi L. Avergun, Esq.
Cadwalader, Wickersham & Taft LLP
1201 F Street, NW
Washington, DC 20004
Counsel for Cardinal Health

Dated: 9/30/08

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Acting Administrator

Dated:

Wendy H. Goggin
Chief Counsel

Dated:

APPENDIX A

APPENDIX A

(Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.

2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.

3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.

4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (Specialty Pharmaceutical).

5. 2512 West Cott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.

6. 500 Jerry Steele Lane, McDonough, Georgia, operating under DEA registration number RC0271267.

7. 14601 County Road 212, Findlay, Ohio, operating under DEA registration number RC0313940.

8. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.

9. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.

10. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.

11. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (Specialty Pharmaceutical).

12. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.

13. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.

14. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.

15. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

16. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.

17. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.

18. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.

19. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.

20. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.

21. 4 Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.

22. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW0263056.

23. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.

24. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.

25. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.

26. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.

27. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (Parmed Pharmaceuticals).

APPENDIX B

[redacted]

DEA ISO for Auburn

[redacted]

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

NOV 2 8 2007

IN THE MATTER OF

Cardinal Health
801 C Street NW, Suite B
Auburn, Washington 98001

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RW0191813, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0191813 is assigned to Cardinal Health's Auburn, Washington, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on January 28, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0191813 at 801 C Street NW, Suite B, Auburn, Washington 98001. DEA number RW0191813 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

a. Respondent's largest purchaser of combination hydrocodone products in 2007, Horen's Drugstore, Inc. ("Horen's Drugstore"), is a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical

purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

b. Despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies such as Horen's Drugstore, and despite the public information readily available to Respondent regarding Horen's Drugstore's association with rogue Internet pharmacy websites, Respondent repeatedly supplied Horen's Drugstore with excessive amounts of hydrocodone. Specifically, Respondent distributed in excess of 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007; including over 116,000 dosage units in July; over 129,000 dosage units in August; and over 122,000 dosage units in September.

c. Respondent, disregarding the clear indications that Horen's Drugstore was engaged in the diversion of controlled substances, distributed unusually large amounts of hydrocodone to Horen's Drugstore. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0191813 is hereby suspended, effective December 3, 2007, at 12:00 p.m. Pacific Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for January 28, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 11/28/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

Date _____ Time _____ Diversion Investigator _____

APPENDIX C

[redacted]

DEA ISO for Lakeland (2007)

[redacted]

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator

Washington, D.C. 20537

DEC 05 2007

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RC0182080, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RC0182080 is assigned to Cardinal Health's Lakeland, Florida, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 9, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA number RC0182080 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From August 2005 through October 2007, Respondent distributed over 8,000,000 dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

3. Many of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

a. Retail pharmacies in Florida order an average of less than 8,400 dosage units of hydrocodone per month. Respondent distributed hydrocodone to pharmacies engaged in the diversion of controlled substances as reflected in the chart below. Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.

Pharmacy	Total Dosage Units	Number of Months Distributions Made	Monthly Average	Dates of Distribution (*Distributions not made in every month)
Medipharm-Rx, Inc.	620,030	4	155,007	Aug – Dec 05*
DRM Enterprises, Inc.	929,600	22	42,254	Jan 06 – Oct 07
Jen-Mar Pharmacy Services, Inc.	353,700	11	32,154 1st 3 mos: 2,766 Last 8 mos: 43,175	Mar 06 – Feb 07*
Armenia Pharmacy, Inc.	132,900	12	11,075 1st 6 mos: 1,900 Last 6 mos: 20,250	Mar 06 – Feb 07
National Pharmacy, Inc.	659,800	9	73,311	Aug 05 – May 06*
Parulmed Corporation	468,400	20	23,420	Aug 05 – Apr 07*
Q-R-G, Inc.	1,213,200	5	242,640	Feb – June 06
RKR Holdings, Inc.	741,000	13	57,000	Aug 05 – Jan 07*
United Prescription Services, Inc.	1,148,100	4	287,025	Jul – Oct 06
Satellite Drug and Pharmacy	1,044,000	19	54,947 1st 4 mos: 375 Last 15 mos: 69,500	Feb 06 – Oct 07*

b. Respondent distributed hydrocodone to the pharmacies identified in subparagraph 3.a, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from the

Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

c. Respondent distributed hydrocodone to each of the pharmacies named in subparagraph 3.a, above, and to other pharmacies engaged in Internet diversion schemes, in amounts that far exceeded the legitimate needs of its customers.

d. On September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for the Respondent, sent an email to DEA's E-Commerce Section stating that the Respondent had discontinued its sales of controlled substances to 13 suspected Internet pharmacies. Included in Respondent's report of discontinued accounts was the aforementioned RKR Holdings, Inc. ("RKR"). On that same date, Respondent distributed 200 dosage units of combination hydrocodone products to RKR. From September 1, 2006, to January 31, 2007, Respondent distributed 393,600 dosage units of combination hydrocodone products to RKR.

4. Respondent repeatedly supplied the pharmacies named in paragraph 3.a, above, and other pharmacies, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding many of its pharmacy customers' association with rogue Internet pharmacy websites, and despite the suspicious nature of the orders placed by these pharmacies. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective December 10, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 9, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/5/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

_____ _____ _____
Date Time Diversion Investigator

APPENDIX D

[redacted]

DEA ISO for Swedesboro

[redacted]

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

IN THE MATTER OF

DEC 0 7 2007

Cardinal Health
1120 Commerce Blvd.
Swedesboro, NJ 08085

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0269654, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0269654 is assigned to Cardinal Health's Swedesboro, New Jersey, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 7, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

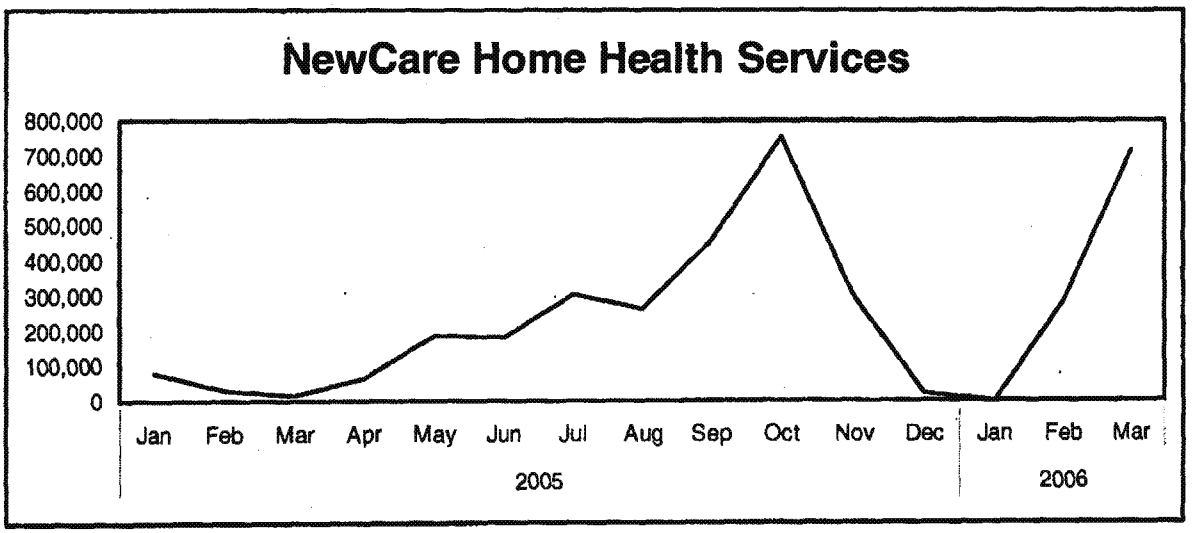
1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0269654 at 1120 Commerce Blvd., Swedesboro, New Jersey 08085. DEA number RW0269654 will expire on May 31, 2008.

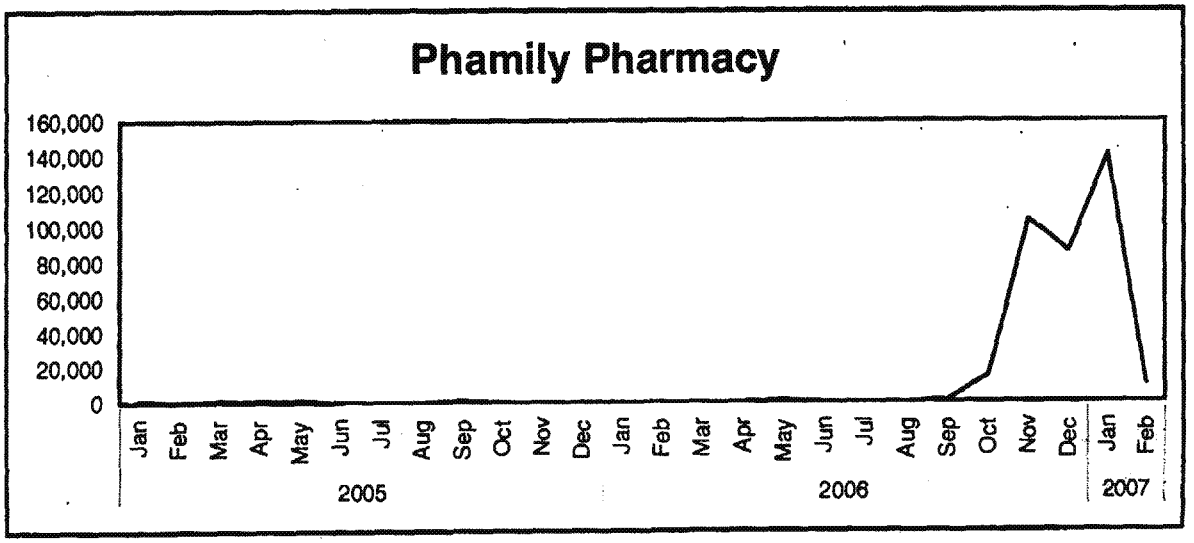
2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From January, 2005 through August, 2007, Respondent distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

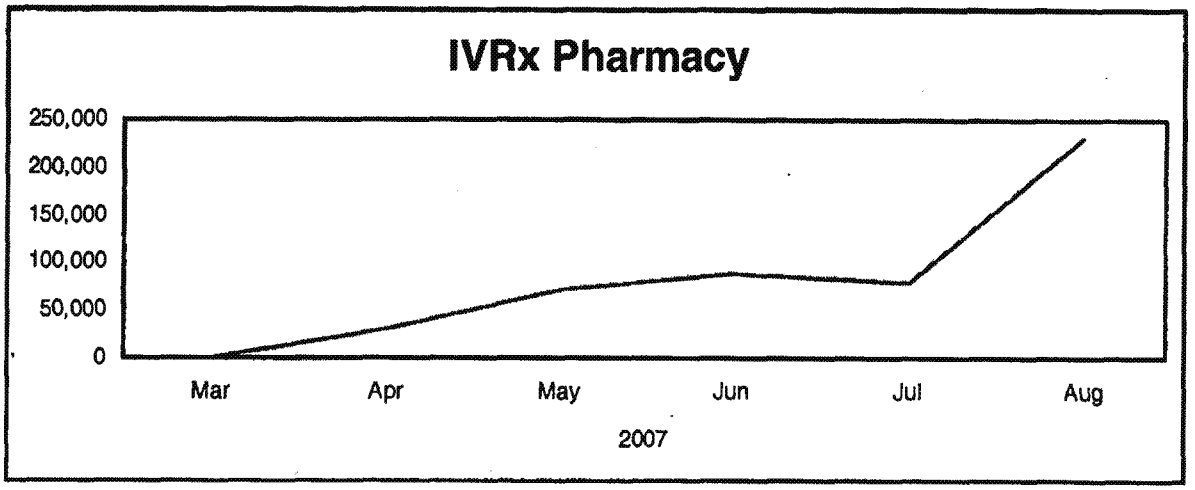
3. Some of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported

prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from drug distribution websites, in violation of applicable Federal and State law. *See United Prescription Services, Inc.*, 72 Fed. Reg. 50,397 (2007).

4. Respondent repeatedly distributed hydrocodone combination products to pharmacies engaged in the diversion of controlled substances, i.e., NewCare Home Health Services, Phamily Pharmacy and IVRx Pharmacy. Respondent continually supplied these pharmacies with excessive amounts of hydrocodone under circumstances in which Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels. The following graphs reflect the total dosage units of hydrocodone combination products that Respondent distributed to each pharmacy.







5. Respondent distributed hydrocodone to the pharmacies identified in paragraph 4, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

6. Respondent repeatedly supplied the pharmacies named in paragraph 4, above, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding the pharmacies' association with drug distribution websites, and despite the suspicious nature of the orders placed by these pharmacies. *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0269654 is hereby suspended, effective December 13, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 7, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's position on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/7/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX E

[redacted]

DEA Show Cause for Houston

[redacted]

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JAN 3 0 2008

IN THE MATTER OF

Cardinal Health
13651 Dublin Court
Stafford, Texas 77477

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Cardinal Health ("Registrant") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, at a place and time to be determined, (if Registrant requests such a hearing), as to why DEA should not revoke DEA Certificate of Registration, RC0333524, pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Registrant's continued registration is inconsistent with the public interest. DEA Certificate of Registration RC0333524 is assigned to Cardinal Health's Stafford, Texas Distribution Center. The basis for this Order to Show Cause is set forth in the following non-exhaustive summary of facts.

1. Registrant is registered with DEA as a distributor in Schedules II-V under DEA number RC0333524 at 13651 Dublin Court, Stafford, Texas 77477. DEA number RC0333524 will expire on May 31, 2008.

2. Registrant distributed massive amounts of particular controlled substances to retail pharmacy customers without maintaining adequate controls to detect and prevent the diversion of controlled substances. For example, from January 2007 through September 2007, Registrant distributed nearly 21 million dosage units of hydrocodone to its retail pharmacy customers. Despite distributing such a large quantity of hydrocodone – a highly addictive and widely abused schedule III controlled substance – Registrant did not have sufficient policies and procedures in place to detect and prevent diversion; did not execute those policies and procedures that were in effect; and failed to provide its employees with the necessary training and resources to detect and prevent diversion.

3. Registrant's distributions of controlled substances to Richmond Pharmacy, AK Pharmacy, and others, were under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances.

4. Notwithstanding the large quantities of controlled substances ordered by these pharmacies, Registrant failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. Moreover, Registrant continued to supply the pharmacies with controlled substances without conducting due diligence, notwithstanding that the pharmacies were ordering controlled substances in quantities that far exceeded what traditional retail pharmacies order; that the pharmacies were ordering controlled substances on a more frequent basis than Registrant's traditional retail pharmacy customers; and that Registrant was supplying an inordinate amount of controlled substances versus non-controlled substances to these pharmacies.

5. The direct and foreseeable consequence of Registrant's failure to conduct appropriate due diligence was the likely diversion of millions of dosage units of particular controlled substances.

6. Despite Registrant's policy limiting a retail pharmacy customer's purchases of hydrocodone products to 800 dosage units a day, Registrant frequently distributed hydrocodone in quantities that greatly exceeded this limit. Registrant, however, rarely scrutinized these purchases, and in the few instances where Registrant investigated a particular order, it was frequently done by employees with little or no training in the prevention and detection of diversion and/or by employees with a direct financial interest in the successful completion of the transaction.

7. From January 2, 2007 through September 11, 2007, Registrant distributed approximately 1,381,500 dosage units of hydrocodone to Richmond Pharmacy, or approximately 160,000 dosage units each month. During that period, Registrant distributed hydrocodone to Richmond on 142 days. On each of those days, Richmond's purchase of hydrocodone exceeded the daily limit set by Registrant for its retail pharmacy customers. More recently, on each of the eight days in September in which Registrant shipped hydrocodone to Richmond, Richmond grossly exceeded Registrant's threshold of hydrocodone distributions without scrutiny by Registrant's employees. Registrant distributed 66,000 dosage units of hydrocodone to Richmond on September 4, 2007; 6,000 dosage units on September 5, 2007; 12,000 dosage units on September 6, 2007; 18,000 dosage units on September 7, 2007; 48,000 dosage units on September 10, 2007; 24,000 dosage units on September 11, 2007; and 12,000 dosage units on September 12, 2007. Additionally, on September 17, 2007, Registrant shipped 12,000 dosage units of hydrocodone to Richmond, despite having been notified on September 14, 2007, that Richmond surrendered its DEA registration on September 13, 2007, and was no longer authorized to order or dispense controlled substances.

8. Registrant likewise failed to scrutinize the ordering practices of other retail pharmacy customers who exceeded their monthly limit of hydrocodone purchases and other controlled substances, and continued to distribute massive amounts of controlled substances to these customers despite the fact that these customers routinely exceeded, by huge margins, their monthly limit for purchases of particular controlled substances.

THE following procedures are available to Registrant in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause Registrant may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Registrant fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Registrant may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Registrant's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Registrant decline to file a request for a hearing or, should Registrant request a hearing and then fail to appear at the designated hearing, Registrant shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX F

[redacted]

2008 Settlement Agreement - Civil Case

[redacted]

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of New Jersey, Middle Florida, Southern Texas, Western Washington, Colorado, Northern Georgia, and Central California ("United States") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Attachment A to this agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

RECITALS

1. Cardinal is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, Cardinal operates numerous distribution facilities in the United States, including the seven facilities more fully described in Attachment B to this Agreement ("the Seven Facilities").

2. As described in Attachment A, Cardinal holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from each of its distribution facilities that handle controlled substances, including the Seven Facilities described in Attachment B.

3. Cardinal is required to operate the Seven Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the CSA").

4. Each of the Seven Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective jurisdictions as stated in Paragraph 8.

5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.

6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. *See* 21 U.S.C. § 871 *and* 28 C.F.R. § 0.55(c).

7. Hydrocodone is a medication whose manufacture, distribution, sale and possession is regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).

8. The "Covered Conduct" shall mean the following alleged conduct:

A. Within the District of New Jersey: From January 2005 through August 2007, Cardinal-Swedesboro sold more than 4.5 million dosage units of hydrocodone to three pharmacies (IVRx Pharmacy in Springfield, New Jersey; Newcare Home Health Services in Baltimore, Maryland; and Phamily Pharmacy in Washington, D.C.), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

B. Within the Middle District of Florida: From August 2005 through October 2007, Cardinal-Lakeland sold more than 8 million dosage units of hydrocodone to ten pharmacies in the Tampa area (Medipharm-Rx, Inc., DRM Enterprises, Inc., Jen-Mar Pharmacy Services, Inc., Armenia Pharmacy, Inc., National Pharmacy, Inc., Parulmed Corporation, Q-R-G-, Inc., RKR Holdings, Inc., United Prescription Services, Inc., and Satellite Drug and Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

C. Within the Southern District of Texas: From March 2006 through September 2007, Cardinal-Stafford sold more than 7.5 million dosage units of hydrocodone to fifteen pharmacies in the Houston area (Richmond Pharmacy, AK Pharmacy, Farmacia de Medica, Parkway Pharmacy, Farmacia del Pueblo, Magnum Road Pharmacy, Mastery Pharmacy, Amex Pharmacy #3, Local Pharmacy, HP Pharmacy, I-10 East Pharmacy, Xavier Pharmacy, TXRX Pharmacy, Park Place Pharmacy, and King's Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

D. Within the Western District of Washington: From March 2007 through November

2007, Cardinal-Auburn sold more than 900,000 dosage units of hydrocodone to Horen's Drugstore, Inc., in Burlington Washington and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

E. Within the District of Colorado: From January 2006 through February 2006, Cardinal-Denver sold large quantities of hydrocodone to Hometown Pharmacy in Trinidad, Colorado, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

F. Within the Northern District of Georgia: From April 2007 through October 2007, Cardinal-McDonough sold large quantities of hydrocodone to Poly-Plex Pharmacy in Atlanta, Georgia, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

G. Within the Central District of California: From September 2006 through January 2007, Cardinal-Valencia sold large quantities of hydrocodone to Boulevard Pharmacy in Sun Valley, California, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5).

9. By entering into this Agreement, Cardinal does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing.

10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)) authorized the imposition of a civil penalty of up to $25,000 for most violations of Section 842, but, violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to $10,000 for each violation.

11. To avoid the delay, expense, inconvenience, and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against Cardinal under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.

12. This Agreement is neither an admission of liability by Cardinal nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

TERMS AND CONDITIONS

13. Cardinal shall pay to the United States the sum of Thirty-Four Million Dollars ($34,000,000) (the "Settlement Amount") within thirty (30) days of the effective date of this Agreement, payable as follows:

A. For Conduct Alleged to have Occurred within the District of New Jersey: Cardinal shall pay the sum of Three Million Dollars ($3,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of New Jersey, pursuant to instructions provided by the United States.

B. For Conduct Alleged to have Occurred within the Middle District of Florida: Cardinal shall pay the sum of Sixteen Million Dollars ($16,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Middle District of Florida, pursuant to instructions provided by the United States.

C. For Conduct Alleged to have Occurred within the Southern District of Texas: Cardinal shall pay the sum of Eight Million Dollars ($8,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Southern District of Texas, pursuant to instructions provided by the United States.

D. For Conduct Alleged to have Occurred within the Western District of Washington: Cardinal shall pay the sum of Three Million Five Hundred Thousand Dollars ($3,500,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Western District of Washington, pursuant to instructions provided by the United States.

E. For Conduct Alleged to have Occurred within the District of Colorado: Cardinal shall pay the sum of One Million Dollars ($1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Colorado, pursuant to instructions provided by the United States.

F. For Conduct Alleged to have Occurred within the Northern District of Georgia: Cardinal shall pay the sum of One Million Five Hundred Thousand Dollars ($1,500,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Northern District of Georgia, pursuant to instructions provided by the United States.

G. For Conduct Alleged to have Occurred within the Central District of California: Cardinal shall pay the sum of One Million Dollars ($1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Central District of California, pursuant to instructions provided by the United States.

14. In consideration of the undertakings by Cardinal, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842 against Cardinal, its officers, directors, and employees for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.

15. Cardinal fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following:

A. Any potential criminal liability;

B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);

C. Any administrative liability, including mandatory exclusion from any federal programs;

D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and

E. Any claims based on such obligations as are created by this Agreement.

17. Cardinal acknowledges that each of its DEA registered facilities is required to comply

with the controlled substance record keeping and reporting requirements of the CSA. Cardinal represents that it has taken good-faith actions to detect and prevent diversion including agreeing to implement the policies and procedures that are the subject of an administrative settlement agreement between it and DEA.

18. Cardinal agrees that any and all costs it has or will incur in connection with this matter -- including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action -- shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP reimbursement purposes.

19. This Agreement is not intended by the Parties to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

20. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between Cardinal and an Office of the United States Attorney signing this Agreement, exclusive jurisdiction and venue shall lie in the federal judicial district of the Office with whom the dispute arose, and to the extent that state law applies to the dispute, the law of the State within the jurisdictional district shall apply. If a dispute arises under this Agreement between Cardinal and more than one of the United States Attorney's Office signing this Agreement, exclusive jurisdiction and venue shall lie in the District of New Jersey and to the extent that state law applies to the dispute, the law of the state of New Jersey shall apply.

21. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.

22. This Agreement constitutes the entire agreement between the Parties and cannot be

amended except in writing and when signed by all the Parties to this Agreement.

23. Cardinal acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.

24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

25. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

On Behalf of Cardinal Health:

R. Kerry Clark
Chairman and Chief Executive Officer

9/30/2008
Date

Ivan K. Fong
Chief Legal Officer and Secretary

Sept. 30, 2008
Date

John J. Carney, Esq.
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Counsel for Cardinal Health

09-30-08
Date

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9/30/08
Date

On Behalf of the United States of America:

Christopher J. Christie
United States Attorney
District of New Jersey

By: Alex Kriegsman
Assistant United States Attorney

Date: 10/2/08

Robert E. O'Neill
United States Attorney
Middle District of Florida

By: Javier Guzman
Assistant United States Attorney

Date: 9/30/08

Donald J. DeGabrielle, Jr.,
United States Attorney
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By: Jill Venezia
Assistant United States Attorney

Date: 09/30/2008

Jeffrey C. Sullivan
United States Attorney
Western District of Washington

By: Anastasia Bartlett
Assistant United States Attorney

Date: 9/30/2008

Troy A. Eid
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Amanda Rocque
By: Amanda Rocque
Assistant United States Attorney

9-29-08
Date

David E. Nahmias
United States Attorney
Northern District of Georgia

Mina Rhee
By: Mina Rhee
Assistant United States Attorney

9-29-08
Date

Thomas P. O'Brien
United States Attorney
Central District of California

Shana Mintz
By: Shana Mintz
Assistant United States Attorney

Sept. 29, 2008
Date

ATTACHMENT A

ATTACHMENT A

(Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.

2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.

3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.

4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (Specialty Pharmaceutical).

5. 2512 West Cott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.

6. 500 Jerry Steele Lane, McDonough, Georgia, operating under DEA registration number RC0271267.

7. 14601 County Road 212, Findlay, Ohio, operating under DEA registration number RC0313940.

8. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.

9. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.

10. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.

11. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (Specialty Pharmaceutical).

12. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.

13. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.

14. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.

15. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

16. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.

17. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.

18. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.

19. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.

20. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.

21. 4 Cardinal Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.

22. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW02630056.

23. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.

24. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.

25. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.

26. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.

27. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (Parmed Pharmaceuticals).

ATTACHMENT B

ATTACHMENT B

(Seven Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 1120 Commerce Boulevard in Swedesboro, New Jersey ("Cardinal-Swedesboro"), located within the District of New Jersey and operating under DEA registration number RW0269654;

2. 2045 Interstate Drive in Lakeland, Florida ("Cardinal-Lakeland"), located within the Middle District of Florida and operating under DEA registration number RC0182080;

3. 13651 Dublin Court in Stafford, Texas ("Cardinal-Stafford"), located within the Southern District of Texas and operating under DEA registration number RC0333524;

4. 801 C Street NW, Suite B in Auburn, Washington ("Cardinal-Auburn"), located within the Western District of Washington and operating under DEA registration number RW0191813;

5. 4875 Florence Street in Denver, Colorado ("Cardinal-Denver"), located within the District of Colorado and operating under DEA registration number RW0263549;

6. 500 Jerry Steele Lane in McDonough, Georgia ("Cardinal-McDonough"), located within the Northern District of Georgia and operating under DEA registration number RC0271267; and

7. 27680 Avenue Mentry in Valencia, California ("Cardinal-Valencia"), located within the Central District of California and operating under DEA registration number RW0216449.